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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,209	12/18/2000	Jaan Noolandi	D/A0489	4337

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04/05/2004

EXAMINER

DAWSON, GLENN K

ART UNIT PAPER NUMBER

3761

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/740,209

Applicant(s)

NOOLANDI ET AL.

Examiner

Glenn K Dawson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12 is/are allowed.
- 6) ☒ Claim(s) 1-7,9-11,14-17 and 19 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,2,5 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Khuri-Yakub-5028937.

Khuri-Yakub discloses an ink-jet printing device having acoustic lenses focused on a surface of ink, which cause ink droplets to be delivered by capillary action. The lenses focus energy generated by transducers. The ink is placed under pressure and delivered to an area where the lenses focus the energy to a surface of the ink to produce the droplets. See col. 2 lines 41-51; col. 3 lines 30-31 and 49-53. Even though the device is used to make ink droplets, the device would work in the same manner to produce droplets of medication if the fluid used were a medicament instead of ink. The portion 45 shown in fig. 3 could be placed in a human orifice.

Claims 1-3,5-7,11 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Sweet-5231426.

Sweet discloses an ink-jet device where transducers produce energy which is focused by spherical or Fresnel lenses onto the surface of pressurized ink to produce

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droplets. A multiplexer 41 excites a sequence of transducers to produce energy. The frequency range is 5-300MHz. Surface 27 of fig. 4 could be placed in a human orifice.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 3,4,6 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khuri-Yakub-'937 in view of Sweet-'426 and Biegelsen-6136210.

Khuri-Yakub discloses the invention as claimed with the exception of the type of lenses, the 2<sup>nd</sup> driver and lens, and the distance of the lens from the surface of the fluid. Sweet discloses a plurality of the Fresnel and spherical lenses and associated transducers. Biegelsen discloses the use of "plastic" spherical lenses. Sweet also discloses that the distance from the lens to the surface of the fluid is adjustable to match the focal point of the lens being used. It would have been obvious to have used fresnel and plastic spherical lenses as the lens in Khuri-Yakub's device as they have been shown to an effective acoustic lens in droplet delivery devices. To provide a series of driving transducers and associated lenses has been shown to be effective to deliver droplets of fluid from variable source points and would therefore have been an obvious modification. To have made the distance from the lens to the surface of the fluid in the claimed range would have been obvious in the event that the lens used produced an effective focal length within the claimed distance. See col. 2 lines 41-51; col. 3 lines 30-31 and 49-53.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sweet-'426 in view of Biegelsen-'210.

Sweet discloses the invention as claimed with the exception of the spherical lenses being plastic. Biegelsen discloses the use of plastic spherical lenses-see col. 3 lines 11-14.

To have made the lenses of Sweet out of plastic would have been obvious, as it has been shown that such a material is used to manufacture acoustic lenses and is in great abundance for manufacturing purposes.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sweet-'426 in view of Takayama, et al.-5912679.

Sweet discloses the invention as claimed with the exception of the frequency. Takayama discloses the use of 10MHz frequency in an acoustic ink-jet printer-see col. 16 lines 52-64. It would have been obvious to have used the claimed frequency of under 15MHz, as taught by Takayama, as this has been shown to produce desirable ink droplet sizes.

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sweet-'426.

Sweet discloses the invention as claimed with the exception of the specific distance from the lens to the surface of the ink. Since Sweet also discloses that the distance from the lens to the surface of the fluid is adjustable to match the focal point of the lens being used, to have made the distance from the lens to the surface of the fluid in the claimed range would have been obvious in the event that the lens used produced an effective focal length within the claimed distance. The smaller the distance, the larger the droplets produced. In some cases somewhat larger droplets would be desirable in order to make larger print.

Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser-'828 in view of Sweet-'426 and Ivri-'999.

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Hauser discloses the invention as claimed with the exception of the distance from the lens to the surface of the fluid being in the claimed range and the circuit.

Sweet discloses that the distance from the lens to the surface of the fluid is adjustable to match the focal point of the lens being used. To have made the distance from the lens to the surface of the fluid in the claimed range would have been obvious in the event that the lens used produced an effective focal length within the claimed distance. The smaller the distance, the larger the droplets produced. In some cases somewhat larger droplets would be desirable in order to treat areas of the respiratory tract which are closer to the mouth or nose entrances.

Ivri discloses a circuit which senses inhalation and gates the sensing of inhalation with the actuation of the transducers in an aerosol delivery device.

It would have been obvious to have provided the device of Hauser with a circuit tied to a flow sensor for actuation of droplet-forming transducers, as Ivri has disclosed that such a feature allows for the gating of inhalation with the actuation of the transducers, and thus the aerosol-generating step allows for the effective delivery of medication only during inhalation which eliminates actuation during times at which the medication would not be breathed in sufficiently to reach the affected areas of the body, thus wasting medication and medicating healthy tissues.

***Allowable Subject Matter***

Claim 12 is allowed.

Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Response to Arguments***

Applicant's arguments filed 10-31-03 have been fully considered but they are not persuasive.

Applicant argues that the Sweet and Khuri-Yakub references do not disclose a pharmaceutical product. While this is true, it is also irrelevant, since the applicant does not claim the product either. The references to the product in the claims are purely functional or intended use. At no time is the product positively recited.

Applicant also argues that one skilled in the art would not be led to combine the references since they are from ink printing and pharmaceutical dispersion fields. This argument is not persuasive since the applicant maintains throughout the specification that the basic systems used to disperse the pharmaceutical products are indeed prior art ink-jet systems. Indeed, the only prior art reference mentioned in the specification is an ink-jet system. Also note the reference to Voges-5894841, which states that the preferred embodiment of an inhaler uses ink-jet technology-see col. 3 line 62-col. 4 line 1 and col. 4 lines 34-67. Clearly, the technology of ink-jet systems is pertinent to the atomizer/nebulizer pharmaceutical dispersion system proposed by the applicant; the only difference being the solution being dispersed. However, as pointed out above, the solution is not positively recited.



***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K Dawson whose telephone number is 703-308-4304. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Glenn K Dawson  
Primary Examiner  
Art Unit 3761

Gkd  
29 March 2004